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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/868,215	06/14/2001	Monika Junghans	WFG/12544	6039

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EXAMINER

SHEINBERG, MONIKA B

ART UNIT PAPER NUMBER

1634

DATE MAILED: 08/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

### Application No.

09/868,215

### Applicant(s)

JUNGHANS ET AL.

### Examiner

Monika B Sheinberg

### Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 28-33 and 35-53 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 28-33 and 35-53 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *Detailed Action*.

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**DETAILED ACTION**

**Response to Amendment filed 06 June 2003**

Applicants' arguments, filed 06 June 2003, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

**Claim Rejections - 35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

- Claims 28-33 and 35-53, are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolfert *et al.* (*Gene Therapy*, 1996) in view of Hanson *et al.* (WO 95/25809; 28-Sept-1995), and further in view of Wu *et al.* (WO 93/04701; 18-March-1993) and Zobel *et al.* (*Antisense Nuc. Acid. Drug Devel.*, 1997).

This rejection is maintained with respect to claims 28-33, 35-50 for reasons of record and newly applied to claims 51-53. Applicants argue that none of the references applied describe the relative proportions required by claim 38 to make the particle are taught. However the instant

limitation of adjusting molar ratios of protein to nucleic acid, is not a requirement of claims 28-33, 35, 36, 48-51 and 53. As such the argument does not apply to these claims.

Applicants argue that Wolfert *et al.* does not provide any motivation to combine the indicated references. As per the applicants' interpretation of Wolfert *et al.* of the motivation statement selected by the examiner, the reason for using a polycation such as polylysine was due to the better toxicity tolerance of its lower molecular weight. One of ordinary skill in the art would have motivated to use equivalently low molecular weight polycations such as that of arginine for the same reason of decreasing toxicity as per Wolfert *et al.*

Applicants further argue that Hanson *et al.* does not demonstrate the production of synthetic particles because the reference prevents the particle precipitation purposely by the addition of chaotropic agents. However, this argument does not apply to the particle itself (claims 28-33, 35, 36 and 51) and the method of using (48-50 and 53); wherein the particle itself whether or not in a salt-free environment, exists as per the requirements of the particle claimed in claims 28-33, 35, 36, 48-51 and 53. In regards to claims 37-47 and 52, Hanson *et al.* performs the process of particle formation in a salt-free environment with a subsequent addition of salt (p. 32, lines 8-20); and allows for the manipulation of the solution in the "judicious use" of chaotropic agents (p. 29, lines 29-32). The use of "comprising" claim language allows for additional steps to occur thus the claims encompass the subsequent addition of salts. It is also noted that the particles formed as per Wolfert *et al.* are demonstrated to be "always formed in water" (p. 272, 2<sup>nd</sup> column, 3<sup>rd</sup> paragraph).

Applicants argue that Zobel *et al.* does not mention the use of arginine. However the reference was not relied on for the use of arginine but for the motivation to alter surface charge to compress the particle to the required size limitations as suggested by Wolfert *et al.* It is also noted that the desired surface charges are attained through the variation of oligonucleotide and particle ratios (bridging paragraph of pp. 484-485) thus rendering the argument non-persuasive of the reference failing to adjust molar ratios of protein to nucleic acid for surface charge.

With respects to the new claims 28, 48, 51 and 53, the use of a protein that comprises more than 50% or 60% arginine is demonstrated by the utilization of protamine (also required by claims 29 and 49) as previously described in the previous action mailed 29 January 2003.

Therefore, the arguments are non-persuasive to overcome the rejection.

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**Conclusion**

- Claims 28-33, 35-53, are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolfert *et al.* in view of Hanson *et al.*, and further in view of Wu *et al.* and Zobel *et al.* –maintained.

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

***Inquiries***

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Monika B. Sheinberg, whose telephone number is (703) 306-0511. The examiner can normally be reached on Monday-Friday from 9 A.M to 5 P.M. If attempts to reach the examiner by telephone are unsuccessful, the primary examiner in charge of the prosecution of this case, Jehanne Souaya, can be reached at 703-308-6565. If attempts to reach the examiners are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703) 308-1119.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Patent Analyst, Chantae Dessau, whose telephone number is (703) 605-1237, or to the Technical Center receptionist whose telephone number is (703) 308-0196.

August 25, 2003  
Monika B. Sheinberg  
Art Unit 1634

MS

*Jehanne Souaya*  
JEHANNE SOUAYA  
PATENT EXAMINER  
*August 25, 2003*